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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,084	03/31/2004	Stephen T. Flock	D6462CIP2	7354

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EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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05/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,084	Applicant(s) FLOCK ET AL.	
	Examiner AARON ROANE	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 13, 15-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 13, 15-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/22/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 13, 15-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Gordon (U.S. Patent 4,889,120) in view of Sawyer (U.S. Patent 5,824,015) in further view of Hedge et al. (U.S. Patent 6,656,174).

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Regarding claims 1-5 and 22, Gordon discloses a method of treatment for one or more tissue substrates in an individual, comprising: securing the tissue substrates proximal to a ferromagnetic metal susceptor; applying radiofrequency energy that generates a magnetic field to said substrate(s) or to said susceptor or to a combination thereof to inductively generate heat therein; and affixing said substrates together via said heat thereby effecting treatment, see abstract, col. 2:28 - col. 3:62. Gordon fails to explicitly recite controlling the affixing of said substrates via feedback monitoring of a property of said susceptor, said energy or a combination thereof, wherein said property is heat, an electrical property, eddy currents, conductivity, or frequency changes or a combination thereof. It is well known in the art that the connection of different portion of biological tissue can be effected by the crosslinking of collagen, wherein two portions of biological tissue are placed in abutment with each other and heated by various means: laser, RF, microwave, resistive heating, etc. (well known in the art) in order to achieve the crosslinking. It is important that the heating (i.e. temperature obtained by tissue) be high enough to achieve the crosslinking but not so high as to damage and/or ablate the tissue. Sawyer discloses a method for welding biological tissue and teaches that it is well known in the art to denature of collagen containing substances and/or tissues (interpreted as including crosslinking collagen) by heating the substances and/or tissues to a temperature of 45° C to 75° C in order to form tissue welds/seals, see col. 2:27 – col. 3:25 in general and col. 3:46-65 in particular. Hedge et al. disclose and device and method for heat treating biological tissue with RF energy and teach “the interior electrodes 48 and temperature sensing elements 26 are electrically coupled to the respective RF generator 18 and

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controller 19, allowing RF power to be delivered to the inflatable chambers 36, and thus, the targeted tissue, under temperature-feedback control,” see col. 8:65 – col. 9:2 and figures 1 and 5. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon, as taught by Sawyer, to provide a particular heating temperature range for the treated tissue site in order to achieve a collagen crosslinked tissue seal/weld, and as further taught by Hedge et al., to provide the system with temperature sensors and temperature-feedback control in order to obtain and maintain a particular tissue treatment site temperature (tissue/substrate heat).

Regarding claims 6 and 7, Gordon discloses the substrates may be further secured by a surgical fastener in the form of 2 to 3 sutures, see col. 6:29-31.

Regarding claims 8 and 9, Gordon discloses the claimed invention, see col. 3:8-25 and col. 6:43-48 and claims 1-4, particularly claim 4.

Regarding claims 13, 15-18, Gordon discloses the claimed invention, see col. 5:48-65.

Regarding claims 19 and 20, Gordon discloses the claimed invention, see col. 2:1-18 and col. 2:44-53.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) in view of Sawyer (U.S. Patent 5,824,015) in further view of Hedge et al. (U.S.

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Patent 6,656,174) as applied to claim 1 above, and in view of Aida et al. (U.S. Patent 5,897,495).

Regarding claim 11, Gordon in view of Sawyer and further in view of Hedge et al. disclose the claimed invention except for explicitly reciting the radio frequency energy is applied in pulses. It is well known in the art that radio frequency may be applied in a continuous duration or in discrete pulses. Aida et al. disclose a system and method of heat-treating tissue and teach "a transmitter coil for transmitting radio frequency pulses to the treatment target portion such that the thermal treatment can be applied to the treatment target portion by the heat induced by the radio frequency pulses," see col. 12:56-60 and figure 9. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon in view of Sawyer and further in view of Hedge et al. disclose, as taught by Aida et al., to provide radio frequency energy in pulses in order to heat-treat tissue.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) in view of Sawyer (U.S. Patent 5,824,015) and in further view of Hedge et al. (U.S. Patent 6,656,174) as applied to claim 22 above, and still in further in view of Eggers et al. (U.S. Patent 5,366,443).

Regarding claims 23 and 24, Gordon in view of Sawyer in further view of Hedge et al. disclose the claimed invention except for heat is monitored via infrared optical detection. It is extremely well known in the art to provide temperature sensors in various

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alternate/equivalent means such thermistors and infrared optical sensors for example.

Eggers et al. disclose a medical device and method and teach “the temperature sensing may be achieved using fiber optics with infrared sensing technique, a thermocouple, a thermistor or other temperature sensing means,” see col. 11:34-42. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon in view of Sawyer in further view of Hedge et al., as taught by Eggers et al., to provide the device and system with fiber optics with infrared sensing technique (optical infrared sensing) in order to provide specific example of temperature sensing means.

Response to Arguments

Applicant's arguments filed 01/28/2010 have been fully considered but they are not persuasive.

Regarding Applicant's arguments/remarks on page 9, 1st full paragraph, in response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992),

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and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, As all three references treat tissue by heating (albeit to possibly different degrees and or temperatures), one of ordinary skill would appreciate the utility of the combination, the large amount of overlap between the references and therefore readily find and maintain the motivation to combine.

Regarding Applicant's arguments/remarks on page 9, 2nd full paragraph, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Regarding Applicant's arguments/remarks on page 10, 1st full paragraph, the claim language recites "controlling the affixing of said substrate(s) via feedback monitoring of a property of said susceptor, said energy or a combination thereof" which does not preclude the interpretation of monitoring the temperature of the tissue surrounding the susceptors and the susceptors in aggregate, which is a monitoring a property of the susceptor.

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Next, regarding Applicant's arguments/remarks on page 10, 2nd full paragraph, There is nothing taking from the Hedge et al. patent or used in the combination that destroys the teachings of the other references or renders the prior art unsatisfactory for its intended purpose. Applicant is focused in with laser beam intensity on the ablation disclosed by Hedge et al. and seemingly ignored the factor that the only portion of the Hedge et al. invention combined with the other prior art is the temperature measurement/monitoring. Again, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. *In re Bozek*, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Due to the RCE, this action is made non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769